

PATENT
Docket No. 290252016600

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Assistant Commissioner for Patents, Washington, D.C. 20231, on March 10, 2000.

Hazel M. Raskowitz
Hazel M. Raskowitz

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the application of:

Christopher G.M. KEN and Abhijit
ACHARYA

Serial No.: 08/736,896

Filing Date October 25, 1996

For: DETACHABLE MULTIDIAMETER
VASOOCCLUSIVE COIL

Examiner: W. Lewis

Group Art Unit: 3731

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BRIEF ON APPEAL

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This is an Appeal from the final rejection of claims 1, 3 and 4 in the above-referenced application. In accordance with 37 C.F.R. § 1.192, this Brief, along with the Appendix, is filed in triplicate and is accompanied by the required fee set forth in 37 C.F.R. §1.17(c).

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I. Real Party in Interest

The Real Party in Interest in this Appeal is Target Therapeutics, Inc., a Delaware Corporation. The assignment was recorded in the U.S. Patent and Trademark Office on March 20, 1997 at Reel 8427, Frame 0325.

II. Related Appeals and Interferences

Appellant believes that there are no related appeals or interferences which would directly affect or be directly affected by or have a bearing on the Board's decision in this pending appeal.

III. Status of Claims

As listed in the attached Appendix, claims 1, 3 and 4 stand finally rejected and are the subject of this Appeal. Claim 2 has been cancelled. No claims stand allowed.

IV. Status of Amendments

Appellant believes that the amendment filed August 30, 1999 in response to the final Office Action dated May 9, 1999 (Paper No. 19) has been entered by the Examiner.

V. Summary of Invention

This invention is a vasoocclusion helical coil, a medical device that is intended for placement in vessels, typically using a catheter, to block the vessel or to fill a vascular cavity such as an aneurysm. Specification, page 1, lines 7-14. Coils such as the one presently claimed may be placed at the desired site by loading the coil into the lumen of a catheter whose distal end is located at the site. *Id.* at 1, lines 16-17. The coil is then advanced through the catheter lumen using a pusher and expelled from the distal end of the catheter. *Id.* at 1, lines 17-18. Another

method involves detachably coupling the coil to the distal end of a wire, advancing the assembly to the site using a catheter, and uncoupling the coil from the wire at the site. *Id.* at 1, lines 18-20.

Detachable coils carry a member on their proximal end that detachably engages or interlocks with a member on the distal end of the wire. *Id.* at 1, lines 23-24. A problem experienced with such coils is that the member carried on the coil is oriented tangentially to the helical diameter of the coil. *Id.* at 1, lines 23-25. As such, when the coil is decoupled, the member extends tangentially outwardly from the helix diameter and may engage the vessel wall. Such engagement may injure or even perforate the vessel wall. *Id.* from page 1, line 26 to page 2, line 3.

The present invention overcomes this problem by winding the coil in such a way that the two ends project inwardly after the coil is deployed. This is done by providing a soft, flexible helical vasoocclusion coil having a distal end 12, a proximal end 13, and a main body 14. *Id.* at 3, lines 9-10; page 4, lines 3-5; Figures 2-3. While the coil 10 comprises a multiplicity of windings 11 having a first diameter D immediately adjacent the distal end and the proximal end, the coil 10 is also wound into a second diameter d , smaller than the first diameter D , at the proximal end and the distal end. *Id.* at 4, lines 3-5; Figure 3. Each of the proximal and distal ends is positioned radially inwardly of the immediately adjacent first diameter D . *Id.* at 4, lines 5-7; Figure 2. This allows the coil 10 to occlude a vessel or cavity within which it is placed in a way in which it is less likely for the ends 12, 13 to injure the vessel or cavity wall. *Id.* at 4, lines 7-8.

The proximal end 13 of the coil 10 is adapted to detachably couple to the distal end of an elongated wire. *Id.* at page 4, lines 8-11; *see also* Figures 2-3. In particular, the proximal end may have a coupling member that is adapted to detachably interlock with the distal end of an elongated wire, such as slotted member 15. *Id.*

The invention also may comprise the coil 10 as described above in an assembly with an elongated wire having a distal end that carries a coupling member that is detachably coupled to a second coupling member on the proximal end 13 of the coil 10. *Id.*

VI. Issue on Appeal

The following is the lone issue on appeal:

1. Whether claims 1, 3 and 4 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over German Patent DE 3203410 A1 to Heinke et al. in view of U.S. Patent No. 5,639,277 to Mariant et al.?

VII. Grouping of Claims

The claims within each group of claims herein appealed stand or fall together.

VIII. Argument

A. Claims 1, 3 and 4 Are Not Unpatentable Over German Patent DE 3203410 A1 to Heinke et al. Under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,639,277 to Mariant et al.

1. Summary of Rejection

Claims 1, 3 and 4 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over German Patent DE 3203410 A1 ("Heinke et al.") in view of U.S. Patent No. 5,639,277 ("Mariant et al."). The Examiner maintains:

Heinke et al. disclose an [sic] coil (1) having proximal and distal ends that are radially inward relative to the center section. However, Heinke et al. do not disclose the detachable ends. Mariant et al. teach of this element (see Figure 14) in the same field of endeavor for the purpose of allowing proper placement of the coil. It would have been obvious to one skilled in the art at the time of the invention to have placed the attachment means taught by Mariant at [sic] al. onto the Heinke et al. device in order to allow proper and controlled placement of the coil.

Regarding Applicant's arguments, "immediately adjacent" appears to mean "beside". The Heinke et al. reference clearly shows this feature. Regarding the arguments of combination, the problem of maintaining and controlling a coil is well known in the prior art. See the Sepetka '437, Engelson '916 and Palermo '071 references. Mariant et al. teaches of TWO [sic] techniques to aid in the placement of the coil.

Final Office Action (Paper No. 19), May 9, 1999.

In addition, the Examiner noted in the Interview Summary (Paper No. 20), August 12, 1999:

Mr. Revelos [applicant's attorney] pointed out that it was unclear from the figures if [sic] the Heinke et al. reference if the ends of the device were radially inward. Examiner pointed out that as cited by the claims, the spiral shape of the Heinke et al. reference meets the limitations.

2. The Examiner Has Failed to Make A *Prima Facie* Case of Unpatentability Under 35 U.S.C. § 103(a)

"A claimed invention is unpatentable if the differences between it and the prior are 'are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.'" In re *Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999) (citing 35 U.S.C. § 103(a) (Supp. 1998)).

To reject claims in an application under section 103(a), the Examiner bears the burden of first establishing a *prima facie* case of obviousness. When the references cited by the Examiner fail to do so, the rejection is improper and must be overturned. In re *Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995). On appeal to the Board of Patent Appeals and Interferences, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness. In re *Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

The phrase in section 103(a) "at the time the invention was made" prohibits the Examiner from entering into the forbidden zone of hindsight. Selecting and combining prior art references without evidence of a suggestion, teaching or motivation to do so is clearly prohibited. To wit:

Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one to "fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher".

In re *Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999) (quoting *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (citations omitted).

A *prima facie* case of unpatentability of claims 1, 3 and 4 under 35 U.S.C. § 103(a) has not been established by the Examiner. The Examiner points to nothing in Heinke et al. and Mariant et al., either alone or in combination, suggesting or teaching claims 1, 2 and 4.

In particular, the Examiner has failed to properly consider the scope and content of the prior art by alleging that Heinke et al. discloses a coil "having proximal and distal ends that are radially inward relative to the center section", an explicit limitation of claims 1 and 4 (and one present in claim 3 by virtue of its dependency from claim 1). Final Office Action, paragraph 3, (Paper No. 19), May 9, 1999.

Appellants respectfully submit that the Examiner has reached this incorrect conclusion only upon applying impermissible hindsight in the absence of any teaching, suggestion, or incentive to do so.

In view of the fact that the presently pending claims are nowhere suggested by the combination of Mariant et al. and Heinke et al., Appellants respectfully petition the Board to consider the following points, each of which Appellants maintain is an independent basis for the patentability of pending claims 1, 3 and 4.

- a) **The Radii of the Distal and Proximal Ends of the Heinke et al. Coils are Turned Radially Outwardly, Not Radially Inwardly as the Examiner Alleges.**

Appellants submit that the Examiner is incorrect in maintaining that the Heinke et al. discloses a coil having proximal and distal ends that are radially inward relative to the immediately adjacent coil diameter. Rather, Appellants believe that one of ordinary skill in the art at the time of the present invention would have concluded that Heinke et al. neither discloses nor suggests such a coil, but rather a coil whose proximal and distal ends are radially outward relative to the immediately adjacent coil diameter.

The Examiner states: "Heinke et al. disclose an [sic] coil (1) having proximal and distal ends that are radially inward to the center section". Final Office Action (Paper No. 19), May 9, 1999. Appellants respectfully disagree. The various views in the Figures of Heinke and the translation of the accompanying text not only do not disclose this "positioned radially inwardly" limitation, it neither suggests such a solution nor the motivation for one.

In the context of the presently pending claims, Heinke et al. is concerned solely with the concept of providing a thickened head, designed as a further wire coil, connected to the helical spring body at one or both ends "in order to increase the sealing effect." Heinke et al. English Translation, p. 2, lines 20-31; p. 3, lines 34-38; Figures 2, 4, 6, 8 and 9. This feature is presumably present to provide a greater profile to the oncoming blood flow when the device is deployed in a vessel than a non-thickened head so to occlude the vessel with greater efficiency. *See* Heinke et al., Figure 9.

The last sentence of the Heinke et al. English Translation reads with respect to Figure 9: "[t]he individual windings telescope into one another and thus to a large extent inhibit the blood flow." *Id.* at 4, lines 19-21. Again, it is clear that this sentence is directed to the occlusive effect the coil demonstrates to inhibit blood flow when deployed in a vessel.

Taken together and with the teaching of Mariant et al. as a whole (Mariant et al. being cited by the Examiner solely as a reference that discloses a coil having a detachable end - *see* Final Office Action, May 9, 1999), these passages would neither have taught nor suggested to one of ordinary skill in the art at the time of the present invention the limitation present in

pending claims 1, 3 and 4 to position either or both ends of the claimed coil radially inwardly. Nowhere in either of these cited references is such a feature suggested.

In particular, the Examiner seems to rely on Figures 7 and 8 of Heinke et al. in concluding that Heinke et al. discloses this limitation. Appellants believe the Examiner has incorrectly concluded that because the diameter of the windings of the Figures 7-8 coil appear to decrease as one moves either proximally or distally from the center of the coil, it must necessarily follow that the proximal and distal ends are radially inturned. Appellants respectfully submit that this is simply not true.

Appellants maintain that the depiction of the ends of each of the coils of Figures 3-9 are in fact turned radially outwardly relative to the immediately adjacent diameter. It is clear that the radius of curvature of each of the coil ends in the Heinke et al. figures 3-9 coils is in fact larger than that of the immediately adjacent winding. It logically follows that the diameters created by the distal and proximal ends of the Heinke et al. Figures 3-9 coils must be larger than those of the respective immediately adjacent windings, and therefore the distal ends must be positioned relatively outwardly. Nothing in the text of Heinke et al. teaches or suggests otherwise.

Because the Heinke et al. coils of Figures 3-9 have ends positioned radially outwardly necessarily means that Heinke et al. fails to suggest another limitation of pending claims 1, 3 and 4: that the coil be wound into a second diameter at the proximal end and the distal end that is smaller than a first diameter immediately adjacent the proximal and distal ends. By having a larger radius of curvature at the proximal end and the distal end in each coil, by necessity, these coils have a second diameter that is larger than the diameter immediately adjacent the proximal and distal ends (i.e. the equivalent of the claimed "first diameter"). This is an additional yet independent basis for the patentability of claims 1, 3 and 4 that the Examiner has overlooked. Appellants therefore respectfully request that the Board reverse the rejection of pending claims 1, 3 and 4 under 35 U.S.C. § 103(a).

b) In the Alternative, Appellants Submit that it Would Have Been Impossible for One of Ordinary Skill in the Art at the Time of the Invention to Ascertain Whether the Distal and Proximal Ends of the Heinke et al. Coils are Turned Radially Inwardly.

In the alternative, if the Board were to disagree with Appellants' position articulated above, Appellants maintain that it is simply impossible to tell whether both the distal and proximal ends of the coils shown in Figures 3-9 of Heinke et al. are turned radially inwardly. There is no suggestion in the text of Heinke et al. to have lead one of ordinary skill in the art to have concluded such at the time of the present invention. Furthermore, the crude longitudinal views of Heinke et al.'s Figures 3-9 coils do not supply any additional information that discloses this limitation or that would have suggested it to one of ordinary skill in the art at the time of the present invention. Appellants believe that the Examiner came to this conclusion only with the benefit of hindsight.

As proffered in the Response to the Final Office Action mailed August 30, 1999 (Paper No. 25), Appellants wish to review two limitations of claims 1 and 4 (and by dependency, claim 3): first, the coil is wound into a second diameter smaller than the first diameter at the proximal end and the distal end; second, each of the proximal and distal ends is positioned radially inwardly of the immediately adjacent first diameter. As an aid in understanding the scope of these limitations, please refer to Figures A and B below:

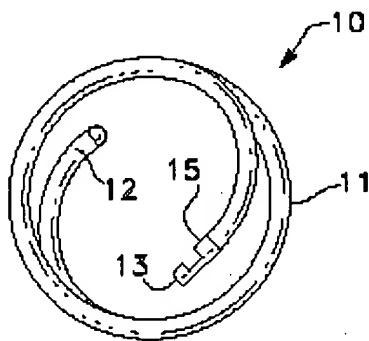


Figure A

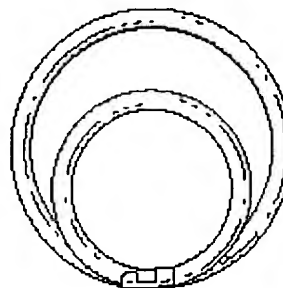


Figure B

These figures represent two different hypothetical coils, each comprising a multiplicity of windings viewed from either a proximal end or a distal end.

Figure A represents a coil identical to that shown in Figure 2 of the present pending application. Note that this embodiment meets each of the two limitations discussed above: the coil is wound into a second diameter smaller than a first diameter at the proximal end and the distal end, and the distal and proximal ends 12 and 13 are positioned radially inwardly of the immediately adjacent first diameter 11.

Figure B, however, is an example of a coil that appears to be wound into a second diameter smaller than a first diameter, but it does not meet the limitation that the proximal (or distal) end be positioned radially inwardly of the immediately adjacent and larger first diameter.

The hypothetical coil shown in Figure B is problematic with respect to a purposes of the present invention as stated in the specification. There is a much greater likelihood that an end of the Figure B coil will catch or snag the interior or intima of a blood vessel or aneurysm, with an accordingly increased likelihood of injury to the vessel wall. In addition, release of the Figure B coil close to the vessel wall raises the potential that the vessel wall will interfere with the uncoupling process. The location of the end of the Figure B coil on the periphery of the coil's secondary structure also has the potential for serving as the *situs* for the formation of a thrombus and its attendant downstream problems.

In the presently pending application, Figure 3 is the coil of Figure 2 (and of Figure A above) viewed from the side. *See, e.g.*, specification at page 2, lines 24-26. With only the side view of Figure 3 in hand, it is impossible for one of ordinary skill in the art to ascertain whether the coil meets the "positioned radially inwardly" limitation of claim 1. In other words, Appellants submit that one of ordinary skill in the art would interpret the Figure 3 elevational

view of the inventive coil, taken alone, could not only be the hypothetical coil of Figure A above, but it also could represent the hypothetical coil of Figure B above.¹

Applicants respectfully submit that the same is true with respect to Heinke et al. It is simply impossible to tell, given only the side views of the coils in Figures 3-9, whether this “positioned radially inwardly” limitation is met. No other figures nor any discussion in the Heinke et al. specification helps. As fully discussed above, without an end view or some supporting description of the Figures 3-9 coils, one of ordinary skill in the art simply would not have been able to tell at the time of the present invention if Heinke et al. suggests, much less discloses, that any of these coils have proximal and distal ends positioned radially inwardly of the immediately adjacent first diameter.

Even if one of ordinary skill in the art at the time of the present invention were to conclude that the Heinke et al. coils could have a smaller proximal and distal diameter than the more interior winding (which Appellants do not concede), it would never have led such a reasonable person to conclude that the “radially inwardly” limitation of claims 1, 3 and 4 is somehow suggested. The example of Figures A and B above proves how it is possible for a coil to have a smaller proximal or distal diameter winding yet not have a proximal or distal end that is positioned radially inwardly of the immediately adjacent first diameter.

Having the presently pending claims in hand, Appellants submit that the Examiner leapt to the conclusion that Heinke et al. and Mariant et al. suggest the claim limitation, when in fact one of ordinary skill in the art at the time the present invention was made could not have done so. Appellants therefore respectfully request that the Board reverse the rejection of pending claims 1, 3 and 4 under 35 U.S.C. § 103(a).

¹ Fortunately, Figure 2 and the enabling description in the present specification clearly teach how the Figure 3 view is to be interpreted. *See, e.g.*, specification page 2, lines 24-26, and page 4, lines 3-9.

c) In the Alternative, Even if the Proximal and Distal Ends of the Heinke et al. Coils in Figures 3-9 are Not Turned Radially Outwardly, Nothing in Heinke et al. Teaches or Suggests the Coil Ends are Turned Radially Inwardly as Required by Pending Claims 1, 3 and 4.

In the alternative, if the Board were to disagree with Appellants' positions detailed above, Appellants maintain that Heinke et al. does not even suggest, much less teach, that its coils are turned radially inwardly as claimed. Appellants contend that the most Heinke et al. suggests is that the radial or proximal ends of its Figures 3-9 coils are merely radially even with, or oriented tangentially to, the immediately adjacent winding.

This interpretation is supported by the lack of any discussion in Heinke et al. with respect to the relative radial position of the ends of the coils shown in Figures 3-9. Please refer to the arguments posited by Appellants above, incorporated herein by reference, detailing this point.

Appellants concede that the last sentence of the Heinke et al. English Translation does disclose that the individual windings of the Figure 9 coil telescope into one another to inhibit blood flow. Heinke et al. English Translation, page 4, lines 19-21. However, there is no discussion nor motivation in Heinke et al. that this telescoping feature has anything to do with the distal or proximal coil ends.

In addition, as previously discussed, Heinke et al. teach this feature in the context of the occlusive effect ("to inhibit blood flow") of the Heinke et al. coil, not in the context of preventing injury to the vessel wall. As Appellants note above, the only discussion in Heinke et al. of the ends of the coils is in the context of providing a thickened head on one coil end (not both ends) to improve the coil's occlusive effect. *See* Heinke et al. English Translation, p. 2, lines 20-31; p. 3, lines 34-38; Figures 2, 4, 6, 8 and 9. Such an improvement in occlusive effect may readily be accomplished by a coil whose end is not turned in radially as presently claimed; the enlarged profile of such a coil end will naturally partially block the interior of the coil to, as Heinke et al. states, "increase the sealing effect." Heinke et al. English Translation, p. 2, lines 20-31.

Accordingly, Appellants respectfully request that the Board reverse the rejection of pending claims 1, 3 and 4 under 35 U.S.C. § 103(a).

**d) The Examiner's Reliance on U.S. Patent No. 5,639,277
(Mariant et al.) as Teaching the Limitation in Claims 1, 3 and 4
of a Vasoocclusion Coil Having Detachable Ends is Immaterial.**

Appellants respectfully submit that for the reasons given above in each of the arguments proffered as to why Heinke et al. neither discloses nor suggests the limitations of claims 1, 3 and 4 as discussed, the reliance on Mariant et al. is immaterial.

The Examiner cites Mariant et al. as teaching the feature of a detachable end on a vasoocclusive coil in Figure 14. Appellants believe that any number of references could have been cited by the Examiner as teaching this feature and do not argue as to the accuracy of this statement.

However, Appellants submit that solely because Heinke et al. neither teaches nor suggests the limitations in claims 1, 3 and 4 as discussed above, the Examiner has failed to make a *prima facie* case of unpatentability of claims 1, 3 and 4 under 35 U.S.C. § 103(a). Therefore, it is immaterial whether Mariant et al. teaches a coil having a detachable end. Accordingly, Appellants respectfully request that the Board reverse the rejection of pending claims 1, 3 and 4 under 35 U.S.C. § 103(a).

IX. Conclusion

Appellants respectfully submit that the rejection of claims 1, 2 and 4 under 35 U.S.C. 103(a) as being unpatentable over Heinke et al. (German Patent DE 3203410 A1) under 35 U.S.C. § 103(a) in view of Mariant et al. (U.S. Patent No. 5,639,277) should be reversed for the reasons expressed above.

Accordingly, Appellants respectfully request the reversal of all grounds of rejection of pending claims 1, 2 and 4 and the return of the application to the examining group for the allowance of all the pending claims.

The Assistant Commissioner is hereby authorized to charge any additional fees under 37 C.F.R. § 1.17 which may be required by this Brief, or to credit any overpayment, to Deposit Account No. 03-1952 (Attorney docket no. 290252016600).

Dated: March 10, 2000

Respectfully submitted,

By:



William C. Revelos
Registration No. 42,101

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5846
Facsimile: (650) 494-0792

Attached: Appendix
(copy of claims involved in the Appeal)

APPENDIX

CLAIMS ON APPEAL

1. A soft flexible helical vasoocclusion coil for use with a wire having a distal end, said coil having:

- (a) a proximal end adapted to detachably couple to the distal end of the wire;
- (b) a distal end;
- (c) said helical vasoocclusion coil comprising a multiplicity of windings

having a first diameter immediately adjacent said distal end and said proximal end; and

- (d) said helical vasoocclusion coil being further wound into a second diameter smaller than said first diameter at said proximal end and at said distal end, whereby said proximal end and said distal end are positioned radially inwardly of said immediately adjacent first diameter, such that the coil acts to occlude a vessel or a cavity when placed within said vessel or cavity.

3. The coil of claim 1 wherein said proximal end has a coupling member that detachably interlocks with the distal end of the wire.

4. An assembly for use in occluding a vessel or a cavity within a vessel comprising:

- (a) an elongated wire having a distal end that carries a first coupling member;

and

- (b) a soft flexible helical vasoocclusion coil having:

- (i) a proximal end that carries a second coupling member that is detachably coupled to the first coupling member;

- (ii) a distal end;

(iii) said helical vasoocclusion coil comprising a multiplicity of windings having a first diameter immediately adjacent said proximal end and said distal end; and

(iv) said helical vasoocclusion coil being further wound into a second diameter smaller than said first diameter at said proximal end and at said distal end, whereby said distal end and the first coupling member at said proximal end are positioned radially inwardly of said immediately adjacent first diameter, such that the coil acts to occlude a vessel or a cavity within a vessel when placed within said vessel or cavity.